

1712. Adulteration of dextrose in lactate—Ringer's solution. U. S. v. 14 Cases of Dextrose in Lactate—Ringer's Solution. Consent decree of condemnation and destruction. (F. D. C. No. 18003. Sample No. 30774-H.)

LIBEL FILED: October 19, 1945, District of Colorado.

ALLEGED SHIPMENT: On or about September 19, 1945, by the Cutter Laboratories, from Oakland, Calif.

PRODUCT: 14 cases, each containing 6 500-cc. bottles, of *dextrose in lactate—Ringer's solution*.

LABEL, IN PART: "Saftiflask Dextrose 5% W/V in Lactate—Ringer's Solution."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported to possess since it purported to be for intravenous use and it contained undissolved material, whereas an article which purports to be for intravenous use should be free from undissolved material.

DISPOSITION: November 5, 1945. The Cutter Laboratories having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

1713. Adulteration and misbranding of estrogenic substance. U. S. v. 12 Bottles of Estrogenic Substance. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 16187. Sample No. 22140-H.)

LIBEL FILED: May 19, 1945, Southern District of Illinois.

ALLEGED SHIPMENT: On or about December 7, 1944, by the Intramed Co., Inc., from New York, N. Y.

PRODUCT: 12 bottles of *estrogenic substance* at Decatur, Ill.

Examination disclosed that the potency of the product was substantially less than the 50,000 International Units of estrone per cubic centimeter, which it was represented to have.

LABEL, IN PART: (Bottle) "1000 cc. Estrogenic Substance * * * 50,000 I. U./cc."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess.

Misbranding, Section 502 (a), the label statement, "Estrogenic Substance * * * 50,000 I. U./cc," was false and misleading.

DISPOSITION: March 19, 1946. The Intramed Co., Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1714. Adulteration of sodium iodide ampuls. U. S. v. 21 Cartons of Sodium Iodide. Default decree of condemnation and destruction. (F. D. C. No. 17937. Sample Nos. 29944-H, 29945-H, 29947-H, 29948-H.)

LIBEL FILED: October 19, 1945, Northern District of California.

ALLEGED SHIPMENT: Between the approximate dates of April 9, 1943, and March 24, 1945, from Bristol, Tenn.-Va., by the S. E. Massengill Co.

PRODUCT: 7 cartons, each containing 6 ampuls, and 14 cartons, each containing 25 ampuls, of *sodium iodide* at San Francisco, Calif.

LABEL, IN PART: "10 cc [or "20 cc"] Size Sodium Iodide * * * in Distilled Water Intravenous."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Ampuls of Sodium Iodide," a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: November 21, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1715. Adulteration of sodium thiosulfate. U. S. v. 31 Boxes of Sodium Thiosulfate. Consent decree of condemnation and destruction. (F. D. C. No. 15722. Sample Nos. 6391-H to 6393-H, incl.)

LIBEL FILED: March 23, 1945, Southern District of New York.

ALLEGED SHIPMENT: From Indianapolis, Ind.

PRODUCT: 31 boxes, each containing 6 ampuls, of *sodium thiosulfate* at New York, N. Y.

Examination showed that the product, when seized at New York, N. Y., was contaminated with particles of sulfur resulting from the disintegration of the *sodium thiosulfate*, the disintegration probably having occurred after the completion of the manufacturing processes.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Ampuls of Sodium Thiosulfate," a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the official standard since it was not free from undissolved material.

DISPOSITION: On November 7, 1945, Eli Lilly and Co. of Indianapolis, Ind., and New York, N. Y., having appeared as claimant, an agreement was entered into between the claimant and the Government. It contained the following provisions:

"FIRST: At and subsequent to the time of their seizure by the United States Marshal said ampoules of Sodium Thiosulfate contained and now contain, in small quantity, minute particles of undissolved sulphur.

"SECOND: Upon completion of their manufacture, said ampoules of Sodium Thiosulfate were inspected by Claimant and were found by it to be free of undissolved material, and the presence in said ampoules of Sodium Thiosulfate of particles of undissolved sulphur is accounted for by the fact that such sulphur may have precipitated out of solution subsequent to completion by the Claimant of the manufacturing, inspection and packaging thereof. In the case of Sodium Thiosulfate, sulphur not infrequently precipitates out of solution after the same has been properly compounded and prepared.

"THIRD: The allegations of the libel herein are true in that by reason of the presence of the aforesaid minute particles of undissolved sulphur in said ampoules of Sodium Thiosulphate the same are not free from undissolved material.

"AND IT IS FURTHER STIPULATED, CONSENTED AND AGREED that a decree may be entered herein which shall recite the foregoing facts and condemn said ampoules of Sodium Thiosulfate."

On November 14, 1945, judgment of condemnation was entered, reciting the provisions of the above-mentioned agreement and containing a finding by the court that the product was adulterated in that it contained minute particles of undissolved sulfur as described in the agreement. On November 28, 1945, an amended decree was entered, ordering that the product be destroyed.

1716. Adulteration and misbranding of oil of cassia. U. S. v. 1 Can of Oil of Cassia. Default decree of condemnation and destruction. (F. D. C. No. 17181. Sample No. 14776-H.)

LIBEL FILED: September 11, 1945, Northern District of Illinois.

ALLEGED SHIPMENT: On or about April 30, 1945, by Standard Synthetics, Inc., from New York, N. Y.

PRODUCT: 1 10-pound can of *oil of cassia* at Chicago, Ill.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), a volatile oil other than "Oil of Cassia U. S. P." had been substituted in whole or in part for the article.

Misbranding, Section 502 (a), the label statement, "Oil of Cassia Redistilled U.S.P.," was false and misleading as applied to the article.

DISPOSITION: January 18, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1717. Adulteration and misbranding of rhubarb. U. S. v. 1 Bag of Rhubarb. Default decree of condemnation and destruction. (F. D. C. No. 18980. Sample No. 43242-H.)

LIBEL FILED: January 14, 1946, District of Maryland.

ALLEGED SHIPMENT: On or about October 4, 1945, by R. J. Prentiss and Co., Inc., from New York, N. Y.

PRODUCT: 1 bag containing 97 pounds of *rhubarb* at Baltimore, Md. This product consisted of a mixture of about $\frac{1}{3}$ rhapontic rhubarb and $\frac{2}{3}$ Indian rhubarb, with a small proportion of a hybrid of these two varieties. The official product consists of varieties of rhubarb grown in China and Tibet. It does not include rhapontic rhubarb.

LABEL, IN PART: "Rhubarb USP Except For Origin"; (invoiced) "Whole Rhubarb Root USP."